REMARKS

First, it will be noted that claim 1 has been substantially amended, in order to specifically address the structural features of this invention that distinguish it from both Christopher and Greenberg, with such amendments appearing both in the body of the claim, and in the preamble of the claim.

At the outset, it will be noted that the preamble of claim 1 contains statements of intended use.

The Federal Circuit has been consistent that statements of intended use, in apparatus claims, must be given weight, if the preamble "breathes life and meaning into the claim, especially if such limitations in the preamble have counterparts in the body of the claim." In this case, statements in the preamble do have counterparts in the body of the claim. In the preamble, it is stated that the device is for maintaining a patient airway without requiring endotracheal intubation, a laryngeal mask, or a cuffed airway, and which has an end in the pharynx above and spaced from the epiglottis of the patient. In clause (a), that same spacing or size feature is recited so that the distal end of the device be above the epiglottis and a distance from the epiglottis. More importantly, the channels of the device; all three of them, are recited in clauses (b), (c) and (d) to likewise have their distal ends disposed within the pharynx above the epiglottis and at a distance from the epiglottis. Neither Christopher nor Greenberg addresses such features. And these are important features. See numbered paragraph 6 of the Declaration of Dr. Richard H. Epstein provided herewith, wherein it is explained that all endotracheal intubation devices extend well into the trachea, which creates tracheal stimulation well below the location of the epiglottis.

See also numbered paragraph 8 of the Epstein Declaration, which addresses how the present invention avoids such tracheal and laryngeal stimulation and the benefits thereof. See also paragraph 8, wherein Dr. Epstein explains that the present invention has nothing to do with tracheal intubation as do Christopher and Greenberg. Where features of a preamble are present in both the preamble and in the body of the claim, there is an absolute requirement that such features be treated as a claim limitation. See *In re Fritch* 972 F.2d 1260, 1262, 23 USPQ 2d 1780, 1781 (Fed. Cir. 1992)

> The critical language in Fritch's independent claims is that the device is to be, in its entirety, both flexible and "conformable to a ground surface of varying slope". These limitations, although located in the claims' preambles, "are necessary to give meaning to the claim[s] and properly define the invention".

See also *General Electric Co. v. Nintendo Co.* 179 F. 3d 1350, 50 USPQ 2d 1910, 1918 (Fed. Cir. 1999).

> We must, thus, determine whether the preamble breathes life and meaning into the claim, and is incorporated by reference because of language appearing later in the claim, making it a limitation of the claim. *See In re Paulsen* 30 F.3d 1475, 1479, 31 USPQ2d 1671, 1673 (Fed. Cir. 1994) ("Terms appearing in a preamble may be deemed limitations of a claim when they 'give meaning to the claim and properly define the invention'") (quoting *Gerber Garment Tech., Inc. v. Lectra Sys., Inc.* 916 F.2d 683, 688, 16 USPQ2d 1436, 1441 (Fed. Cir. 1990)).

And in *Gerber Garment Technology Inc. v. Lectra Systems, Inc.* 916 F2d 683, 688, 16 USPQ2d 1436, 1441 (Fed. Cir. 1990), the court noted that when a feature appears not only in the preamble but is referenced in the body of the claim, it is integral to the claim itself.

> The cutting blade is "necessary to give meaning" to claims 15 and 16 and "properly define the invention." *Perkin-Elmer,* 732 F.2d at 896, 221 USPQ at 675. The cutting blade appears not only in the preamble, but is referenced repeatedly in the body of the claim. It is integral to the claim itself.

It will also be noted that previous claim 11 has been cancelled, because of inclusion of some of the subject matter thereof, into clauses (c), (d) and (e) of claim 1 as amended.

Additionally, the sizing of the device is recited in clause (f) so as to terminate above the epiglottis and at a distance from the epiglottis, to avoid manipulation of the larynx and subglottic structures during use. The sizing of the device is therefore for a very specific purpose, and is not a simple matter of an obvious variation. Nor could either Christopher or Greenberg be sized to accomplish this purpose, because it is the purpose of each of Christopher and Greenberg to provide an intubation tube that extends well into the trachea and necessarily engages and stimulates the laryngeal inlet and and the epiglottis. As is addressed in paragraph 6 in Dr. Epstein's Declaration, the systems of Christopher and Greenberg are intended for an entirely different purpose; namely for use with a deep level of anesthesia, for substantial operations in which the patient is intended to be deeply anesthetized, which, as is explained in numbered paragraph 7 of the Epstein Declaration, is the antithesis of the device of the present invention. As is addressed in numbered paragraph 8, the present invention has nothing to do with tracheal intubation, as do Christopher and Greenberg.

Moreover, it would not be obvious to modify either Christopher or Greenberg to have the size limitations of the device of the present invention. See specifically, paragraph 9 of Dr. Epstein's Declaration which points out that the disclosures of

Christopher and Greenberg actually teach away from any suggestion of arriving at a device as is set forth in amended claim 1 and that, if one were to seek to shorten the devices of Christopher or Greenberg in order to try to achieve the benefits of the present invention, the devices of Christopher and Greenberg would not function in accordance with the needs of Christopher or Greenberg, which is to allow for a deep level of anesthetization of the patient so that the patient will remain immobile while invasive procedures and/or operations are being carried out. Furthermore, as Dr. Epstein explains, without the deeper endotracheal intubation that is inherent with each of Christopher and Greenberg, the necessary deeper level of anesthetization that is required would not be possible.

Clause (g) of claim 1 goes on to recite that the first, second and third conduits comprise a means whereby the administration of inhalant gas, suctioning and the sampling of gas exhaled by the patient may take place simultaneously through separate conduits. Support for this feature is on page 9, lines 25-27, of the specification. Neither of the Christopher nor Greenberg references teach this feature. In paragraph 10 of his Declaration, Dr. Epstein addresses this feature, as well, in terms of having a permanent additional conduit for suctioning, which is so highly usable when the treating physician is located remotely from the patient and unable to access the patient, for example, while being entirely out of the room from the patient while a high level of radiation takes place. See also numbered paragraph 7 of the Epstein Declaration. While Christopher may teach, in paragraph 0039 of page 3, that suctioning can be provided, such is not the same as providing a separate conduit, for simultaneous suctioning along with sampling and providing inhalant gas, all at the same time. Moreover, as Dr. Epstein addresses in

paragraph 10 of his Declaration, in devices of the Christopher type, an anesthesiologist must be in immediate contact with the patient if additional lumens or catheters are to be inserted during treatment, all of which is quite different than having a conduit for the express purpose of suctioning that can be used when the treating physician is remotely located from the patient and unable to access the patient airway during the course of the radiation treatment. Furthermore, as Dr. Epstein goes on to point out, Christopher is not suitable for maintaining an airway without intubating, or to stay in place if the patient is not being directly attended by someone close to the patient.

It is noted that in the Official Action of June 14, 2006, the Examiner has referenced the seminal case of *Graham v. John Deer Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Among those considerations addressed by the Examiner was whether or not there is available objective evidence of non-obviousness. It is submitted that, in this case, there is very substantial objective evidence of non-obviousness. Dr. Epstein's Declaration and its attachments speak to the extraordinary credentials of Dr. Epstein, his years of experience, his writings in the field, his familiarity with the invention and with the Christopher and Greenberg documents, and his experience. The Declaration and its numerous paragraphs address the subject matter of this invention in detail.

In paragraph 9, Dr. Epstein opines on the non-obviousness of this invention and goes so far as to explain that the disclosures of Christopher and Greenberg actually teach away from any suggestion of arriving at device as set forth in amended claim 1 hereof.

Dr. Epstein goes on, in numbered paragraph 11, to explain, based upon his personal experience, that there has been a need for such a device as is set forth in this application and its claims, for a long time, and that that need has been unfulfilled until the

development of the present invention. Such considerations, such as a long felt but unsolved need and the failure of others, are some of the very secondary considerations addressed by the United States Supreme Court in *Graham v. John Deer Co.*

Accordingly, aside from the structural features that are present in the claims, which are not taught in the prior art, and aside from the explanations of the importance of those features as is apparent from the Epstein Declaration, and aside from the opinions of non-obviousness set forth in the various paragraphs of the Epstein Declaration and the explanations therefore, there are, in this case, secondary considerations of non-obviousness.

For all of the above reasons, it is submitted that claim 1, as amended, is clearly non-obvious over either Christopher or Greenberg, or the combination thereof.

Claims 2-10 and 12-15 are each apparatus claims that depend from and include all the limitations of claim 1, or from claims that, in turn, are dependent from claim 1. Accordingly, each of these dependent claims are submitted to be clearly, properly allowable, just as claim 1 is submitted to be clearly, properly allowable. Certain of the dependent claims require specific comment, such as the structural feature recited in claim 5 of the termination of the third conduit, which is not taught in Christopher or Greenberg. Similarly, claim 6 requires a specific termination length, likewise not taught in the applied prior art.

Claim 7 requires a specific cross-section that is an additional patentable feature.

With respect to claim 10, the specific dimensions are not taught or suggested in either Christopher or Greenberg, such that this claim therefore has an additional reason for patentability.

Claim 12 requires a flexible extension, thereby presenting another reason for non-obviousness.

The right-angled connector of claim 14 presents another specific feature that gives another reason for patentability over the cited art.

The specific dispositions of the conduits, relatively, as are recited in claim 15, present further features for defining patentability.

With respect to claim 16, claim 16 is a method claim, and the connecting steps that are recited must be read in the context of the specific structural features of claim 1, in terms of the simultaneous feature recited in clause (g) of amended claim 1. Nowhere in either Christopher or Greenberg is there suggested the simultaneous connection of an inhalant gas source, a suctioning device and a gas sampling device. Accordingly, while claim 16 should be properly allowable for all of the reasons set forth above with respect to claim 1, the simultaneous connection features recited specifically in clause (16) in conjunction with clause (g) of claim 1, present a novel method not taught or suggested in either of the references.

The rejections of claims 8, 10 and 15 under §112 are noted, and are believed to be obviated by the amendments made to the specification herein.

With respect to claim 8, the closed cross-section is clearly disclosed in Figures 1A, 1B, 1C, 1D, 2A, 2B, 2C, 4A and 4C, and the word "closed" has been added to the paragraph bridging pages 6 and 7 of the specification.

With respect to claim 10, the numerical size of the inner diameter of the conduits has been added to the paragraph on page 7 that is amended herewith, support for the same having been present from the outset in original claim 10.

With respect to claim 15, the "closed" cross-section is amended and supported, as is the similar language of claim 8. With respect to the other feature of claim 15, whereby the first conduit and the second conduit are disposed within the device body, such is clearly already set forth in the specification on page 7, lines 9-11, and shown in Figures 1A, 1B and 1C.

No new matter is added to this application, either in the specification or claims.

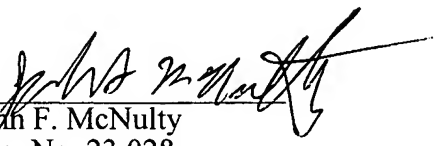
It is submitted that the previous rejections under §112 are now moot.

For all of the above reasons, reconsideration and allowance of all of the remaining claims of this application is respectfully solicited.

If, upon reaching this application, the Examiner should have any questions whatever, the Examiner is invited to telephone applicants' attorney at the number indicated below.

Date:

Respectfully submitted,



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